



CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope, with sufficient postage, addressed to: Commissioner for Patents, Post Office Box 1450, Alexandria, VA 22313, on

May 23, 2005

Date of Deposit

Steven P. Shurtz, Reg. No. 31,424

Name of Applicant, Assignee or
Registered Representative

/Steven P. Shurtz/

Signature

May 23, 2005

Date of Signature

Our Case No.: 1391/1561

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: ROBERT J. YATKA et al.

Serial No.: 10/712,114

Filing Date: November 13, 2003

For: METHOD OF CONTROLLING RELEASE OF
N-SUBSTITUTED DERIVATIVES OF
ASPARTAME IN CHEWING GUM AND GUM
PRODUCED THEREBY

Examiner: Arthur L. Corbin

Group Art Unit No.: 1761

APPEAL BRIEF

Mail Stop Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

This is an appeal from the Final Rejection dated August 19, 2004, of claims 6, 11, 24-27 and 30-31, all the claims pending in the above captioned case.

I. REAL PARTY IN INTEREST

The present application is owned by the Wm. Wrigley Jr. Company.

05/31/2005 MAHNE1 00000015 10712114

01 FC:1402

500.00 DP

II. RELATED APPEALS AND INTERFERENCES

There are no related Appeals and Interferences for this case.

III. STATUS OF CLAIMS

Claims 6, 11, 24-27 and 30-31 are pending. Claims 1-5, 7-10, 12-23 and 28-29 were previously cancelled. Claims 6, 11, 24-27 and 30-31 were all rejected, and are all being appealed. No claims have been allowed.

IV. STATUS OF AMENDMENTS

All previously filed amendments have been entered. An advisory action mailed December 9, 2004 noted that the amendment mailed November 19, 2004 (after the Final Rejection) would be entered upon the filing of a Notice of Appeal. In a telephone conversation with the Examiner on April 26, 2005 the Examiner indicated that the November 19, 2004 amendment and terminal disclaimer overcame the rejections in paragraphs 5 and 9 of the Final Rejection.

V. SUMMARY OF CLAIMED SUBJECT MATTER

The claimed invention relates to producing chewing gum products containing N-substituted derivatives of aspartame. The application discloses various ways of treating the N-substituted derivatives of aspartame to control their release and enhance shelf-life stability. U.S. Patent No. 6,692,778, the patent resulting from the parent of the present application, covers a number of ways of treating the N-substituted derivatives of aspartame. The claims in the present application are directed to two additional treatment methods.

In recent years, efforts have been devoted to controlling release characteristics of various ingredients, such as sweeteners and flavors, in various chewing gum formulations, to thereby lengthen the satisfactory chewing time of the gum and avoid an undesirable overpowering burst of sweetness or flavor during the initial chewing period. In addition, other efforts have been directed at perfecting the use of high-potency sweeteners within the chewing gum formulation, to thereby increase the shelf-life

stability of the ingredients, *i.e.* the protection against degradation of the high-potency sweetener over time. Specification, page 1, lines 14-25

A recently identified class of high-potency sweeteners are N-substituted derivatives of aspartame. Some of these sweeteners may give a long lasting sweetness release when used in chewing gum, while others may give a fast release that may not be compatible with the release of flavor. By modifying N-substituted derivatives of aspartame by various methods, a controlled release from chewing gum can be more effective to balance sweetness with flavor and give a highly consumer acceptable product. The class of N-substituted derivatives of aspartame useful in the present invention are described in U.S. Patent No. 5,480,668. One particularly preferred N-substituted derivative of aspartame is commonly known as neotame. The chemical name of this sweetener is N-[N-(3,3-dimethylbutyl)-L- α -aspartyl]-L-phenylalanine 1-methyl ester. Other preferred N-substituted derivatives of aspartame sweeteners include two other similar chemicals, namely N-[N-[3-(4-hydroxy-3-menthoxyphenyl)propyl]-L- α -aspartyl]-L-phenylalanine 1-methyl ester and N-[N-(3-phenylpropyl)-L- α -aspartyl]-L-phenylalanine 1-methyl ester. Specification, page 1, line 26 to page 2, line 15.

While neotame was suggested for use in chewing gum in the prior art, there was no indication of how the sweetener might release from the chewing gum, and whether its release rate could or should be modified. However, the present inventors speculated that neotame would release slowly from chewing gum during the early stages of mastication of the gum because of its low solubility in water. Therefore, it would be a significant improvement to a chewing gum to have neotame sweetener release its sweetness more quickly along with some of the flavor in the gum, thus balancing the overall taste perception. Specification, page 5, lines 4-11

The present inventors developed methods of controlling the release of N-substituted derivatives of aspartame. Previously mentioned U.S. Patent No. 6,692,778 covers methods of controlling release involving physical modifications of the sweetener by encapsulation with another substrate, such as spray drying, spray chilling, fluid-bed coating and coacervation. These encapsulation techniques that give partial encapsulation or full encapsulation can be used individually or in any combination in a

single step process or multiple step process. Generally, delayed release of sweetener is obtained in multistep processes like spray drying the sweetener and then fluid-bed coating of the resultant powder. Specification, page 6, lines 18-28.

Another method of isolating the N-substituted derivative of aspartame from other chewing gum ingredients is to add the sweetener to the dusting compound of a chewing gum. A rolling or dusting compound is applied to the surface of chewing gum as it is formed. This rolling or dusting compound serves to reduce sticking to machinery as it is formed, reduces sticking of the product to machinery as it is wrapped, and sticking to its wrapper after it is wrapped and being stored. The rolling compound comprises a N-substituted derivative of aspartame in combination with, preferably, mannitol, sorbitol, sucrose, starch, calcium carbonate, talc, other orally acceptable substances or a combination thereof. The rolling compound preferably constitutes from about 0.25% to about 10.0%, more preferably about 1% to about 3% of weight of the chewing gum composition. The amount of N-substituted derivative of aspartame added to the rolling compound is preferably about 0.001% to about 1% of the rolling compound or about 0.1 ppm to about 100 ppm of the chewing gum composition. Specification, page 11, lines 6-19.

Another method of isolating the N-substituted derivative of aspartame is to use it in the coating/panning of a pellet chewing gum. Pellet or ball gum is prepared as conventional chewing gum, but formed into pellets that are pillow shaped, or into balls. The pellets/balls can then be sugar coated or panned by conventional panning techniques to make a unique sugar coated pellet gum. The N-substituted derivative of aspartame is very stable and slightly water soluble, and can be easily added to a hot sugar solution prepared for sugar panning. The N-substituted derivative of aspartame can also be added as a powder blended with other powders often used in some types of conventional panning procedures. Levels of use of the N-substituted derivative of aspartame may preferably be about 2 ppm to about 500 ppm in the coating and about 1 ppm to about 200 ppm of the weight of the chewing gum product. The weight of the coating may preferably be about 20% to about 50% of the weight of the finished gum product. Specification, page 11, line 24 to page 12, line 6.

Thus, in a first aspect, the invention includes a method of producing a chewing gum product containing a N-substituted derivative of aspartame wherein the N-substituted derivative of aspartame is applied as a part of a rolling compound applied on the chewing gum product. See claim 24.

In a second aspect, the invention includes a method of producing a chewing gum product containing a N-substituted derivative of aspartame wherein the N-substituted derivative of aspartame is applied as a part of a coating on a chewing gum pellet. See claim 26.

These methods of using neotame sweetener in the chewing gum can allow a lower usage level of the sweetener, can give the sweetener a more controlled release rate, and can reduce or eliminate any possible reaction of the sweetener with gum base, flavor components, or other components, yielding improved shelf stability. Specification, page 11, lines 19-24, and page 11, line 32 to page 12, line 2.

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

1. Claims 6, 11, 24-27 and 30-31 were rejected under 35 U.S.C. § 112, first paragraph, as not being adequately described in the original specification.
2. Claims 6, 11, 24-27 and 30-31 were rejected under 35 U.S.C. § 103(a) as being unpatentable over U. S. Patent No. 5,480,668 (Nofre) in view of U.S. Patent No. 4,997,659 (Yatka).

VII. ARGUMENT

- A. Claims 6, 11, 24-27 and 30-31 are patentable under 35 U.S.C. § 112, first paragraph, as being adequately described in the original specification.**

In the Final Rejection, claims 6, 11, 24-27, 30 and 31 were rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. According to the Final Rejection, there is no support in the original disclosure for the concept of mixing an additional high-potency sweetener with the N-substituted aspartame derivative before it is applied in the rolling compound or in the coating. This rejection is improper and must be reversed.

1. Claims 24-27 and 30-31

First, claims 24-27, 30 and 31 do not include the limitation that is asserted as not being taught in the original disclosure. These claims should not therefore have even been included in the rejection.

2. Claims 6 and 11

Second, as to claims 6 and 11, which do require an additional high-potency sweetener selected from the group consisting of aspartame, alitame, salts of acesulfame, cyclamate and its salts, saccharin and its salts, sucralose, thaumatin, monellin, dihydrochalcone, glycyrrhizin, stevioside and combinations thereof to be mixed with the N-substituted derivative of aspartame, these claims are adequately described in the original specification. The combination of these other high-potency sweeteners with a N-substituted derivative of aspartame is explicitly taught for other aspects of the invention covered in the parent patent. While there is no example given of mixing a high-potency sweetener with the N-substituted derivative of aspartame for the rolling compound and coating aspects of the invention, the "SUMMERY OF INVENTION" section, where different aspects of the invention are discussed, page 4 lines 7-11 states: "The high-potency N-substituted derivative of aspartame sweetener may also be combined with other high-potency sweeteners including, but not limited to, thaumatin, aspartame, acesulfame K, sodium saccharin, sucralose, alitame, cyclamate, stevioside, glycyrrhizin and dihydrochalcones."

From the context of these lines in the Summery Of Invention, it is clear that this statement refers to all of the different ways that N-substituted derivatives of aspartame are suggested for use in chewing gum. Thus, when pages 11 and 12 describe the aspects of the invention where N-substituted derivatives of aspartame are used in a coating and in a rolling compound, it would be understood that these aspects of the invention also include embodiments where another high-potency sweetener is mixed with the N-substituted derivative of aspartame. Thus the inventions of claims 6 and 11 are adequately described in the original specification.

B. Claims 6, 11, 24-27 and 30-31 are patentable over U. S. Patent No. 5,480,668 (Nofre) in view of U.S. Patent No. 4,997,659 (Yatka).

Claims 6, 11, 24-27, 30 and 31 were rejected in the Final Rejection under 35 U.S.C. §103(a) as unpatentable over U. S. Patent No. 5,480,668 (Nofre) in view of U.S. Patent No. 4,997,659 (Yatka). This rejection is also improper and must also be reversed. Claims 6, 24-25 and 30 require using a N-substituted derivative of aspartame as part of a rolling compound on a chewing gum product. Claims 11, 26-27 and 31 require using an N-substituted derivative of aspartame as part of a coating on a chewing gum pellet. While Nofre discloses the N-substituted derivatives of aspartame used in the present invention, Nofre makes no suggestion for using the disclosed sweeteners in a rolling compound for chewing gum or in a chewing gum coating.

Yatka, on the other hand, discloses different ways of using a completely different sweetener, alitame, in chewing gum. While Yatka discloses using alitame as a part of a rolling compound and in a pellet coating, there is no suggestion in Yatka to use other sweeteners in this fashion. There is no reason from the references themselves to combine the references and treat N-substituted derivatives of aspartame the way alitame was treated. This rejection is thus based on hindsight.

Just because one high-potency sweetener was used in a particular fashion in producing chewing gum does not mean that it would have been obvious to use other high-potency sweeteners in the same fashion. Moreover, alitame was suggested for use in these ways in Yatka because of a desire to delay its release or separate it from other ingredients which may cause the alitame to degrade. The need for delayed release or prevention of degradation has not been shown in the prior art as being applicable to N-substituted derivatives of aspartame. Rather, Nofre shows the stability of the N-substituted derivatives of aspartame disclosed therein when used in chewing gum (see Col. 3, lines 51-60); and there is no suggestion that the materials release too quickly from chewing gum.

The Final Rejection notes that Nofre teaches to mix a N-substituted derivative of aspartame with alitame and then add that mixture into chewing gum. The Final Rejection then goes on to argue that it would have been obvious to use this mixture in place of the pure alitame in the way that Yatka teaches to use the alitame by itself. This

argument is also based on hindsight. The most that a person of ordinary skill in the art would learn from Nofre is to add the mixture to edible products, not even chewing gum specifically. Again, there is no teaching in Nofre to use the mixture in other ways, or to use it in place of alitame in other ways that alitame is used. Nor is there anything in Yotka that teaches to use combinations of sweeteners in place of alitame. There is nothing in Yotka that would suggest treating a combination of alitame and an N-substituted derivative of aspartame the same way that alitame was used, and nothing in Nofre that would suggest looking at Yotka for ideas about how to include mixtures of alitame and an N-substituted derivative of aspartame in chewing gum products. While Yotka teaches to use alitame in a chewing gum coating or in a rolling compound, it does not suggest that any other high-potency sweetener should be mixed with the alitame and used in the same way. The simple fact of the matter is that the combination suggested by the Final Rejection in making the rejection would not have been made without hindsight of the present invention.

In order for a *prima facie* case of obviousness to be established, the teachings from the prior art itself must suggest the claimed subject matter to one of ordinary skill in the art. The mere fact that the prior art could be modified as proposed in the Final Rejection is not sufficient to establish a *prima facie* case of obviousness. The Final Rejection must explain why the prior art would have suggested to one of ordinary skill in the art the desirability of the modification. *See In re Fritch*, 972 F.2d 1260, 1266, 23 USPQ2d 1780, 1783-84 (Fed. Cir. 1992). The Final Rejection gives no reason to make such a combination. The rejection is thus based on impermissible hindsight reconstruction of the invention.

VIII. CONCLUSION

Appellants have made a novel and nonobvious contribution to the art of controlling the release of N-substituted derivatives of aspartame from chewing gum products. The claims at issue distinguish over the cited references. The present invention is not obvious in view the cited prior art. The references are being combined based solely on hindsight reconstruction of the invention. A person of ordinary skill in the art would not combine the references as suggested in the Final Rejection.

Appellants submit that the present invention is fully patentable over the cited references and the Examiner should be REVERSED.

Respectfully submitted,

/Steven P. Shurtz/

Steven P. Shurtz
Registration No. 31,424
Attorney for Appellants

Dated: May 23, 2005

BRINKS HOFER GILSON & LIONE
P.O. Box 10395
Chicago, IL 60610
(312) 321-4200
Direct Dial: (801) 444-3933

APPENDIX A

CLAIMS ON APPEAL

6. The method of Claim 24 wherein an additional high-potency sweetener selected from the group consisting of aspartame, alitame, salts of acesulfame, cyclamate and its salts, saccharin and its salts, sucralose, thaumatin, monellin, dihydrochalcone, glycyrrhizin, stevioside and combinations thereof is mixed with the N-substituted derivative of aspartame before it is applied in the rolling compound.

11. The method of Claim 26 wherein an additional high-potency sweetener selected from the group consisting of aspartame, alitame, salts of acesulfame, cyclamate and its salts, saccharin and its salts, sucralose, thaumatin, monellin, dihydrochalcone, glycyrrhizin, stevioside, and combinations thereof is mixed with the N-substituted derivative of aspartame in the coating.

24. A method of producing a chewing gum product containing a N-substituted derivative of aspartame wherein the N-substituted derivative of aspartame is applied as a part of a rolling compound applied on the chewing gum product.

25. The method of Claim 24 wherein the N-substituted derivative of aspartame is selected from the group consisting of:

a) N-[N-(3,3-dimethylbutyl)-L- α -aspartyl]-L-phenylalanine 1-methyl ester;

b) N-[N-[3-(4-hydroxy-3-menthoxyphenyl)propyl]-L- α -aspartyl]-L-phenylalanine 1-methyl ester; and

c) N-[N-(3-phenylpropyl)-L- α -aspartyl]-L-phenylalanine 1-methyl ester.

26. A method of producing a chewing gum product containing a N-substituted derivative of aspartame wherein the N-substituted derivative of aspartame is applied as a part of a coating on a chewing gum pellet.

27. The method of Claim 26 wherein the N-substituted derivative of aspartame is selected from the group consisting of:

- a) N-[N-(3,3-dimethylbutyl)-L- α -aspartyl]-L-phenylalanine 1-methyl ester;
- b) N-[N-[3-(4-hydroxy-3-menthoxyphenyl)propyl]-L- α -aspartyl]-L-phenylalanine 1-methyl ester; and
- c) N-[N-(3-phenylpropyl)-L- α -aspartyl]-L-phenylalanine 1-methyl ester.

30. The method of claim 24 wherein the N-substituted derivative of aspartame comprises N-[N-(3,3-dimethylbutyl)-L- α -aspartyl]-L-phenylalanine 1-methyl ester.

31. The method of claim 26 wherein the N-substituted derivative of aspartame comprises N-[N-(3,3-dimethylbutyl)-L- α -aspartyl]-L-phenylalanine 1-methyl ester.